DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

November 3, 2004

VIA FEDERAL EXPRESS

Dana C. Leavitt, President
Great Atlantic Trading
563 Seaside Road
Ocean Isle Beach, NC 28469

Warning Letter
05-ATL-04

Dear Mr. Leavitt:

On September 1-3, 2004, investigators from the Food and Drug Administration (FDA), conducted an inspection of your plant located at Ocean Isle Beach, North Carolina. The inspection was conducted to determine your firm's compliance with FDA's regulations for importing and processing fish and fishery products, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR Part 110). During our inspection, the FDA investigators found serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations established under 21 CFR 123. The seafood HACCP regulations were issued pursuant to section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4). Accordingly, your repacked caviar is adulterated, in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations of concern to us are as follows:

1) You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for refrigerated Russian and/or Iranian caviar imported from various European countries.

2) You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed affirmative steps for refrigerated Russian and/or Iranian caviar imported from various European countries that are not adequate. Specifically, your attempts to comply with the affirmative step requirements of the seafood HACCP regulation have included the following: obtaining health certificates from a foreign government or third party but in a foreign language; visiting/inspecting the foreign processor but maintaining no records that document what was observed during the inspection; and periodically conducting chemical and microbiological testing of the imported caviar but failing to maintain on file a copy, in English, of a written guarantee from the foreign processor that the imported caviar is processed in accordance with the requirements of 21 CFR Parts 110 and 123. Health certificates, even if written in English, may not be adequate to satisfy the requirements for an affirmative step. The certificates, either continuing or lot-by-lot, must be from an appropriate foreign government inspection authority or competent third party, and must certify that the imported fish or fishery product was processed in accordance with the requirements of 21 CFR Part 123. The certificates should identify the inspector, the processor, and the product, including lot number if appropriate. All certificates should be signed and dated, and in the case of a continuing certificate, it should include the expiration date of the certificate. If you want to meet the requirements for an affirmative step by regularly visiting and inspecting the foreign processor(s) bear in mind that the person performing the on-site inspection should be competent to perform that task. Competency includes a thorough knowledge of the seafood industry sector, the principles of HACCP, the HACCP regulation, and GMPs. These on-site inspections should be conducted at least on an annual basis, and their findings documented in writing with sufficient detail. If you want to meet the affirmative step requirement by periodically testing the imported fish or fishery product, you must also maintain on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with 21 CFR Part 123. A reasonable frequency for this affirmative step could be testing the first three entries, and if satisfactory, testing quarterly thereon. The written guarantee should be obtained once a year. Records documenting the testing conducted and the results obtained should be kept for official FDA review.

3) You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, during the period of 7/23/04 through 8/2/04, your firm did not follow the monitoring procedure of checking the storage cooler temperature twice daily at the "Cooler Storage" critical control point to control the pathogen hazard listed in your HACCP plan for "Fresh Caviar."

4) You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for "Fresh Caviar" does not list the

food safety hazard of *Clostridium botulinum* toxin formation. After review of your HACCP plan for "Fresh Caviar" and your caviar repacking operation, we find that the above hazard is reasonably likely to occur during the refrigerated storage of your finished product (repacked caviar in reduced oxygen packaging), during its distribution, and throughout its shelf life. It is our understanding that you are currently using time temperature integrators (TTI) when shipping your repacked caviar. However, your current HACCP plan does not include use of TTIs as part of your "shipping" critical control point. Proper use of TTIs, including maintaining documentation of their adequacy, may be effective in controlling the *Clostridium botulinum* hazard throughout the shelf life of these products. Adequacy of the TTIs may be determined via scientific studies conducted by a process authority or equivalent. Your supplier of TTIs may be of assistance in procuring such documentation. Your HACCP plan's critical limits and/or monitoring procedures for the finished product storage and shipping critical control points should be modified so that they cover adequately the *Clostridium botulinum* hazard.

5) You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for "Fresh Caviar" lists a monitoring procedure/frequency at the "Receiving" critical control point that is not adequate to control the pathogen growth hazard. Specifically, your HACCP plan's listings for "How" and "Frequency" for the "Receiving" critical control point are unclear, and thus fail to ensure compliance with the listed critical limit. As a secondary processor of caviar, your responsibility at "Receiving" is to document the product was not subjected to time/temperature abuse while in transit until it comes under your control. This should be properly addressed by your HACCP plan's critical limit and monitoring procedures at this critical control point.

We may take further action if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of products to European Union (EU) countries if you do not correct these deviations. Also, FDA may detain your imported seafood products without examination.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of HACCP plans and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the GMP regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District